REMARKS

Claims 115-126 and 158-163 are amended. New claim 183 is added. Claims 154-157, and 167 are cancelled without prejudice. Claims 115-153, 158-166, and 168-183 are pending in the application. Reconsideration is respectfully requested in view of the above amendments and following remarks. For the Examiner's convenience and reference, Applicants' remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Drawings

Applicants are unable to locate any specific objections to the drawings in their records and respectfully request the Examiner to provide a copy of such objections in the event they were misplaced and Applicants need to specifically address particular deficiencies. A formal set of drawings are submitted herewith for the Examiner's approval.

Objections to Claims

Claims 154-161 and 164-182 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

(i) Claims 154-157, 167 stand rejected for specifying that selected samples are "for use in passive immunotherapy" which is not a positive active method step.

Solely in order to expedite prosecution, claims 154-157, 167 are cancelled in response to the claim objections without prejudice by the Applicants. Applicants reserve the right to file claims corresponding to this subject matter in this or related applications in the future. Therefore, this ground for rejection is presently moot.

(ii) Claims 158-161 stand rejected for specifying that selected samples are "for use in preparation of polyclonal antibodies" which is not a positive active method step. Applicants amend claims 158-161 to positively recite the additional step of "preparing polyclonal antibodies with the selected biological samples." Applicants respectfully request withdrawal of this ground for objection to claims 158-161.

(iii) Claims 164-166, 168-182 stand rejected for specifying that the selection is done to identify a sample for removal from the supply which is not a positive active method step.

Applicants respectfully traverse. Claims 164-166, 168-182 depend from independent claims 115-125, 162 and 163 which specify a method comprising the step of "selecting biological samples." Claims 164-166, 168-182 specify an additional limitation on the selection step in that the "selecting is to identify an HCV positive sample for removal from the supply." Applicants submit that claims 164-166, 168-182 are dependent claims in proper form and respectfully request withdrawal of this ground of objection.

Rejections under 35 U.S.C. § 112, second paragraph

(i) Claims 115-182 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out an distinctly claim the subject matter which applicant regards as the invention. Claims 115-182 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being incomplete for omitting essential steps, such omission amounting to a gap between the steps.

In particular, claims 115-117 stand rejected for failing to specify detection steps for samples that do contain the polynucleotide. Claims 118-129, 162 and 163 stand rejected for failing to set forth detection steps for the polynucleotide or antibodies. Claims 130-182 which depend from these claims also stand rejected under the same grounds.

Applicants respectfully traverse these grounds for rejection. Applicants note that claims 115-125, 162 and 163, as amended, specify "[a] method of selecting biological samples from a supply of biological samples comprising selecting from said supply those samples that" meet one or more specified criteria. In other words, the invention relates to "selecting" samples from a supply of biological samples those samples that meet the specified criteria and not to methods for determining whether an individual sample possesses certain characteristics. For example, claims 118-119 specify that the samples are selected on the basis of whether they "comprise either (i) a polynucleotide that hybridizes under stringent conditions to a contiguous sequence . . . or (ii)

antibodies that form an antigen-antibody complex with an HCV polypeptide sequence . . ." Claims 120-122 specify selection based on the presence in the sample of polynucleotides that hybridize under stringent conditions, while claims 123-125 specify selection based on the presence in the sample of the specified antibodies. None of the methods claimed in independent claims 115-125, 162 and 163, as amended rely on any specified detecting method as a critical feature of the claimed invention. The only limitation of the biological samples is that they do (or do not) possess a specified attribute. The physical determination of such attributes is not part of the claimed invention.

As specified in section 2172.01 of the MPEP cited by the Examiner, "a claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention." Claims that define the metes and bounds of the claimed invention with a reasonable degree of precision and particularity are definite as required by the second paragraph of section 112. *In re Venezia*, 530 F.2d 956, at 958, 189 USPQ 149 (CCPA 1976) ("We see nothing wrong in defining the structures of the components . . . in terms of the interrelationship of the components, or the *attributes they must possess*." (emphasis added). *Id.* at 959); *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968)).

The present Specification enables the determination of the specified attributes of the selected samples by describing detection of polynucleotides and antibodies by providing several general methods for detecting polynucleotides comprising specific sequences (*see* e.g., Specification pp. 172:28 – 177:32, 191:17 – 192:21) and antibodies against specific antigens (*see* e.g., Specification pp. 178:1 – 179:24, 181:14 – 184:19, 192:23 – 194: 17). Applicants note that the Examiner has not rejected these claims for lack of enablement in the disclosure. However, nowhere are these methods specified to be essential for the claimed "selecting" step.

The Examiner does not indicate anywhere in the Specification any admission by Applicants that a particular detection method is critical for the claimed "selecting" step. In the

event that this rejection is maintained, Applicants respectfully request the Examiner to provide an affidavit specifying parts of the Specification where "selecting" is linked to specific detection methods for polynucleotides.

Likewise, the methods of claims 118-129, 162 and 163 specify selecting biological samples based on a specific attribute of the biological samples and the present Specification does nowhere state that a particular method for detecting the specified features of the polynucleotide or antibodies is related to the selection process. In the event that this rejection is maintained, Applicants respectfully request the Examiner to provide an affidavit specifying parts of the Specification where "selecting" is linked to specific detection methods for polynucleotides or antibodies.

Applicants respectfully submit that claims 115-117 and 118-129, 162 and 163 particularly point out an distinctly claim the subject matter which Applicants regard as the invention as only non-critical steps are omitted from the claims. Therefore, Applicants respectfully request withdrawal of this ground for rejection of claims 115-117 and 118-129, 162 and 163 and claims 130-182 which depend from them.

(ii) Claims 150-153 and 167 stand rejected for allegedly lacking sufficient antecedent basis for the limitation "samples that are not selected . . ." in reference to claim 132 and others. Claims 150-153 and 167 depend from claims 132, 133, 138, 139 and 144 which ultimately depend from independent claims 115-125, 162 and 163.

Applicants respectfully traverse the Examiner's rejection. The methods of claims 115-125, 162 and 163 specify "selecting biological samples from a supply of biological samples comprising selecting from said supply those samples that comprise . . ." The step of "selecting biological samples" from a supply clearly implies that some members of the "supply of human biological samples" will NOT be selected because they do NOT comprise the specified attribute. Thus, the basis for the limitation "samples that are not selected . . ." is inherently provided in

independent claims 115-125, 162 and 163. Therefore, Applicants respectfully request withdrawal of this ground for rejection.

(iii) Claims 158-161 stand rejected for claiming samples for preparation of polyclonal antibodies when the claims 115-125, 162 and 163, from which claims 158-161 depend specify detection of polynucleotides.

Applicants respectfully traverse the Examiner's characterization of independent claims 115-125, 162 and 163 which forms the basis for this rejection. Claims 115-125, 162 and 163 are not directed towards detection of polynucleotides or antibodies. Instead, they specify methods for "selecting biological samples" based on specific attributes of the biological samples. The method of claims 115-125, 162 and 163 result in a selection of biological samples which, in turn, can be employed in the "preparation of polyclonal antibodies." Since the preparation of polyclonal antibodies from the selected biological samples is enabled, Applicants respectfully request withdrawal of this ground for rejection.

(iv) Claims 154-157 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants cancel claims 154-157. Therefore this ground for rejection is moot.

Double Patenting Rejections

Claims 118, 119, 123-125, 129-132, 136-138, 142-144, 148-150, 152, 154-158, 160, 161, 164, 167, 169, 170, 171, 175-177, 181 and 182 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 5,350,671. The Examiner finds that the claims are not patentably distinct from each other because they both allegedly perform the same detecting steps using the same methods.

Applicants respectfully traverse. The method of the claims specify "selecting biological samples" that have been detected for the presence of certain polynucleotides or antibodies. The

"detecting" step is presumably carried out separately from, and prior to, the selection step. U.S. Patent No. 5,350,671 does not claim a selection step. Therefore, Applicants respectfully request withdrawal of this ground of rejection.

If maintained, Applicants will overcome this ground for rejection with a terminal disclaimer once the Examiner has indicated the allowability of the claims.

CONCLUSION

In light of the Amendments and the arguments set forth above, Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned. If the Examiner determines that the claims are not allowable, Applicants request an opportunity to interview the Examiner.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**".

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 223002006313.

Respectfully submitted,

Dated: February 19, 2002

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Title:

Please delete "HCV IMMUNOGENS AND IMMUNOGENIC COMPOSITIONS" and insert therefor: --PROCESS FOR SCREENING FOR HCV--.

In the Claims:

115. (Amended twice) A method of selecting biological samples from [human individuals, said method comprising selecting from] a supply of [human] biological samples[,] comprising selecting from said supply those samples that contain a detectable polynucleotide comprising a contiguous sequence of at least 15 nucleotides fully complementary to either strand of Figure 3.

116. (Amended twice) A method of selecting biological samples from [human individuals, said method comprising selecting from] a supply of [human] biological samples[,] comprising selecting from said supply those samples that contain a detectable polynucleotide comprising a contiguous sequence of at least 15 nucleotides fully complementary to either strand of Figure 62A.

117. (Amended twice) A method of selecting biological samples from [human individuals, said method comprising selecting from] a supply of [human] biological samples[,] comprising selecting from said supply those samples that contain a detectable polynucleotide comprising a contiguous sequence of at least 15 nucleotides fully complementary to either strand of Figure 89.

118. (Amended twice)A method of selecting biological samples from [human individuals, said method comprising selecting from] a supply of [human] biological samples[,] comprising selecting from said supply those samples that comprise either (i) a polynucleotide that hybridizes under stringent conditions to a polynucleotide that comprises a contiguous sequence of at least 15 nucleotides from the genome of a hepatitis C virus genome or the complement thereof, or (ii) antibodies that form an antigen-antibody complex with an amino acid sequence of at least 10 contiguous amino acids encoded by a hepatitis C virus genome.

119. (Amended twice) A method of selecting biological samples from [human individuals, said method comprising selecting from] a supply of [human] biological samples[,] comprising selecting from said supply those samples that comprise either (i) a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides from either strand of at least one of the HCV cDNA inserts in a lambda gt-11 cDNA library deposited as ATCC No. 40394 or (ii) antibodies that form an antigen-antibody complex with an HCV polypeptide sequence of at least 10 contiguous amino acid encoded by an HCV cDNA insert in the lambda gt-11 library deposited as ATCC deposit No. 40394.

120. (Amended twice) A method of selecting biological samples from [human individuals, said method comprising selecting from] a supply of [human] biological samples[,] comprising selecting from said supply those samples that comprise a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides found in either strand of Figure 89.

121. (Amended twice) A method of selecting biological samples from [human individuals, said method comprising selecting from] a supply of [human] biological samples[,] comprising selecting from said supply those samples that comprise a polynucleotide that

hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides found in either strand of Figure 14.

122. (Amended twice) A method of selecting biological samples from [human individuals, said method comprising selecting from] a supply of [human] biological samples[,] comprising selecting from said supply those samples that comprise a polynucleotide that hybridizes under stringent conditions to a contiguous sequence of at least 15 nucleotides from either strand of at least one of the hepatitis C virus (HCV) cDNA inserts in [the] a lambda gt-11 cDNA library deposited as ATCC No. 40394.

123. (Amended twice)A method of selecting biological samples from [human individuals, said method comprising selecting from] a supply of [human] biological samples[,] comprising selecting from said supply those samples that comprise antibodies that form an antigen-antibody complex with an amino acid sequence of at least 10 contiguous amino acids found in Figure 90.

124. (Amended twice) A method of selecting biological samples from [human individuals, said method comprising selecting from] a supply of [human] biological samples[,] comprising selecting from said supply those samples that comprise antibodies that form an antigen-antibody complex with an amino acid sequence of at least 10 contiguous amino acids found in Figure 14.

125. (Amended twice) A method of selecting biological samples from [human individuals, said method comprising selecting from] a supply of [human] biological samples[,] comprising selecting from said supply those samples that comprise antibodies that form an antigen-antibody complex with a hepatitis C virus (HCV) polypeptide sequence of at least 10

contiguous amino acid encoded by an HCV cDNA insert in [the] a lambda gt-11 library deposited as ATCC deposit No. 40394.

126. (Amended twice) A method according to any of claims 118-122 wherein said selected samples comprise said polynucleotide and said stringent conditions permit the formation of a stable hybrid duplex between said polynucleotide and said contiguous sequence and do not permit the formation of a stable duplex between said contiguous sequence and the genomes of Hepatitis B or Hepatitis A viruses.

158. (Amended twice) A method according to claim 132 [wherein said samples are for use in the preparation of polyclonal antibodies] further comprising preparing polyclonal antibodies with the selected biological samples.

159. (Amended twice) A method according to claim 133 [wherein said samples are for use in the preparation of polyclonal antibodies] further comprising preparing polyclonal antibodies with the selected biological samples.

160. (Amended twice) A method according to claim 138 [wherein said samples are for use in the preparation of polyclonal antibodies] further comprising preparing polyclonal antibodies with the selected biological samples.

161. (Amended twice) A method according to claim 142 [wherein said samples are for use in the preparation of polyclonal antibodies] further comprising preparing polyclonal antibodies with the selected biological samples.

162. (Amended once) A method of selecting biological samples from [human individuals, said method comprising selecting from] a supply of [human] biological samples[,] comprising selecting from said supply those samples that contain a detectable polynucleotide comprising a sequence that is fully complementary to a contiguous sequence of at least 15 nucleotides from the genome of a hepatitis C virus genome or the complement thereof.

163. (Amended once) A method of selecting biological samples from [human individuals, said method comprising selecting from] a supply of [human] biological samples[,] comprising selecting from said supply those samples that contain a detectable polynucleotide comprising a sequence that is fully complementary to a contiguous sequence of at least 15 nucleotides from either strand of at least one of the HCV cDNA inserts in a lambda gt-11 cDNA library deposited as ATCC No. 40394.

183. (New) A method according to any one of claims 123, 124 or 125 wherein the selected samples comprise antibodies that form an antigen-antibody complex with an amino acid sequence of at least 15 contiguous amino acids.

Claims 154-157, and 167 are cancelled without prejudice.